

DEC 17 2010

510(k) Summary of Safety and Effectiveness

Date:

November 18, 2010

Submitter:

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Device Trade Name:

Unity Network ID

Common /Usual Name:

Physiological Patient Monitor

Classification Names:

21 CFR 870.2300 Monitor, Physiological, Patient (without
arrhythmia detection or alarms)

Predicate Device:

K071982 Unity Network ID

Device Description:

The Unity Network ID system communicates patient data from sources other than GE Medical Systems *Information Technologies*, Inc. equipment to a clinical information system, central station, and/or GE Medical Systems *Information Technologies* Inc. patient monitors.

The Unity Network ID acquires digital data from eight serial ports, converts the data to Unity Network protocols, and transmits the data over the monitoring network to a Unity Network device such as a patient monitor, clinical information system or central station.

Intended Use:

The Unity Network ID is indicated for use in data collection and clinical information management through networks with independent bedside devices. The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

Technology:

The Unity Network ID employs the same functional technology as the predicate device.

Test Summary:

The subject of this 510(k) is a design modification for the Unity Network ID. The Unity Network ID complies with the voluntary standards as detailed in Section 9.2 - Specific Standards and Guidance of this submission. The following quality assurance measures were applied to the development of the Unity Network ID:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Subsystem Verification
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the Unity Network ID is as safe, as effective, and performs as well as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

DEC 17 2010

GE Medical Systems Information Technologies, Inc.
c/o Mr. Robert L. Casarsa
Regulatory Affairs Leader
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K103432
Trade/Device Name: Unity Network ID V6
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: November 22, 2010
Received: November 29, 2010

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K10 3432

Device Name: Unity Network ID

Indications for Use:

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Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K10 3432

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